

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of :

Dennie J.M. van den HEUVEL and :  
Johannes J. PLATTEEuw :

: Group Art Unit:

Divisional Application of :  
Serial No.: 09/833,662 :

: Examiner:

Filed: September 9, 2003 :

For: MODIFIED RELEASE FORMULATIONS CONTAINING A HYPNOTIC  
AGENT**INFORMATION DISCLOSURE STATEMENT**Commissioner for Patents  
Alexandria, Virginia 22313-1450

Sir:

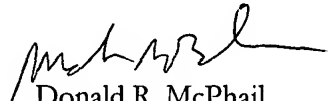
Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

- ☒ 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).
- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(1).

- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(2).
- ☐ c. Attached is our check no. \_\_\_\_\_ in the amount of \$180.00 in payment of the fee under 37 C.F.R. §1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- ☐ 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. \_\_\_\_\_ in the amount of \$180.00 in payment of the fee under 37 C.F.R. §1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).
- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(1).
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(2).
- ☒ 4. Copies of the references were cited by or submitted to the Office in parent application No. 09/833,662, filed April 13, 2001, which is relied upon for an earlier filing date under 35 U.S.C. §120. Thus, copies of these references are not attached. 37 C.F.R. §1.98(d).
- ☐ 5. To the extent necessary, a petition for an extension of time under 37 C.F.R. §1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,  
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|--|--|----------------|----------------|---------------------------------------|----------|---|--|
| <b>LIST OF PRIOR ART CITED BY<br/>APPLICANT</b><br><br><b>(PTO-1449)</b>                                 |  |                |                | ATTY. DOCKET NO.<br><b>SYN-0031D1</b> |          | DIVISIONAL OF<br>APPLN. SERIAL NO.<br><b>09/833,662</b> |  |
|  |  |                |                | APPLICANT(S)<br><b>LEMMENS et al.</b> |          |   |  |
|  |  |                |                | FILING DATE                           |          | GROUP   |  |
| <b>U.S. PATENT DOCUMENTS</b>   |  |                |                |                                       |          |   |  |
| EXAMINER'S<br>INITIALS   | *PATENT NO.  | *ISSUE<br>DATE | *INVENTOR NAME | CLASS                                 | SUBCLASS | FILING<br>DATE  |  |
|  | 3,862,140  | 01/1975        | Zinnes et al.  |                                       |          |   |  |
|  | 4,382,938  | 05/1983        | Kaplan et al.  |                                       |          |   |  |
|  | 4,626,538  | 12/1986        | Dusza et al.   |                                       |          |   |  |
|  | 4,794,185  | 12/1988        | Rossey et al.  |                                       |          |   |  |
|  | 5,292,461  | 03/1994        | Juch et al.    |                                       |          |   |  |
|  | 5,891,891  | 04/1999        | Benincasa      |                                       |          |   |  |
|  | 6,242,460  | 06/2001        | Ettema et al.  |                                       |          |   |  |
|  | 6,281,360  | 08/2001        | Ettema et al.  |                                       |          |   |  |
|  | 6,309,668  | 10/2001        | Bastin et al.  |                                       |          |   |  |
|  | 6,248,363  | 06/2001        | Patel et al.   |                                       |          |   |  |
|  |  |                |                |                                       |          |   |  |
| <b>U.S. PATENT APPLICATION PUBLICATIONS</b>  |  |                |                |                                       |          |   |  |
|  | *PATENT<br>APPLN.<br>PUB. NO.  | *PUB. DATE     | *APPLICANT     | CLASS                                 | SUBCLASS |   |  |
|  |  |                |                |                                       |          |   |  |
| <b>FOREIGN PATENT DOCUMENTS</b>  |  |                |                |                                       |          |   |  |
| EXAMINER'S<br>INITIALS   | PATENT NO.   | DATE           | COUNTRY        | CLASS                                 | SUBCLASS | Translation<br>Yes No                                   |  |
|  | 00/33835   | 06/2000        | WO             |                                       |          |   |  |
|  | 0 050 563  | 05/1984        | EP             |                                       |          |   |  |
|  | 0 251 859  | 11/1990        | EP             |                                       |          |   |  |
|  |  |                |                |                                       |          |   |  |
|  |  |                |                |                                       |          |   |  |
| <b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b> |  |                |                |                                       |          |   |  |
|  | Martine Schmitt et al., <i>Imidazo [1,2-b] pyridazines. XXIII* Some 5-Deaza Analogues. Syntheses of Some 2-Aryl-6-(chloro, methoxy or unsubstituted)-3-(variously substituted)imidazo[1,2-a] pyridazines and Their Affinity for Central and Mitochondrial Benzodiazepine Receptors</i> ; Aust. J. Chem., 50:719-725 (1997) |                |                |                                       |          |   |  |
|  | Giuseppe Trapani et al., <i>Synthesis and binding affinity of 2-Phenylimidazo[1,2-a] pyridazines Derivatives for both Central and Peripheral Benzodiazepine Receptors. A New Series of High-Affinity and selective ligands for the Peripheral Type</i> ; J. Med. Chem., 40:3109-3118, (1997)                               |                |                |                                       |          |   |  |
|  | P. George et al., "Zolpidem and Related Compounds: Syntheses, Physical Properties and Structure Activity Relationships"; <i>Imidazopyridines in sleep disorders</i> ; Raven Press, pp 11-23, (1998)  |                |                |                                       |          |   |  |
| EXAMINER   |  |                |                | DATE CONSIDERED                       |          |   |  |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.